

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellant(s): Malnoe, et al.
Appl. No.: 10/607,330
Conf. No.: 4205
Filed: June 26, 2003
Title: COMPOSITIONS AND METHODS AGAINST INFLAMMATORY
PROCESSES
Art Unit: 1655
Examiner: Deborah A. Davis
Docket No.: 3714652-00365

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated October 7, 2009 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit that the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated August 15, 2008 as noted in Appellants' Appeal Brief filed on May 8, 2009, for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejections of pending Claims 1, 3-4, 6, 8, 10-11, 14, 16 and 63-64 be reversed.

II. THE REJECTION OF CLAIMS 1, 4, 6, 8 AND 10 UNDER 35 U.S.C. § 102(b) SHOULD BE REVERSED BECAUSE *ANANTHARAMAN* DOES NOT DISCLOSE EACH AND EVERY ELEMENT OF THE PRESENT CLAIMS

Appellants respectfully request that the Board reverse the rejections of Claims 1, 4, 6, 8 and 10 under 35 U.S.C. §102(b) because the Examiner has still failed to demonstrate that *Anantharaman* discloses each and every element of the present claims. In contrast, Appellants respectfully submit that *Anantharaman* fails to disclose or suggest each and every element of the present claims.

In the Examiner's Answer, the Examiner asserts that "*Anantharaman* et al. anticipates the instant claims by disclosing a gelatinized cereal product comprising chicory plant material" and that "[t]here is not difference in the cited composition and the instant claims." See, Examiner's Answer, page 7, lines 2-7. However, Appellants respectfully disagree. Indeed, independent Claim 1 recites, in part, a composition comprising a therapeutically effective amount of a thermally extruded plant material that includes one or more phytochemical agents capable of inhibiting at least one of enzymatic and transcriptional activity to inhibit inflammation in a mammal, wherein the one or more phytochemical agents is selected from the group consisting of sesquiterpene lactones.

As discussed in detail in Appellant's Appeal Brief, any thermally extruded plant material of *Anantharaman* cannot "include" sesquiterpene lactones where the entire goal of *Anantharaman* was to "remove or destroy" the sesquiterpene lactones and wherein *Anantharaman* explicitly discloses that HPLC analysis of the pellets of *Anantharaman* resulted in "[n]o sesquiterpene lactones [being] detected" for free sesquiterpene lactones, for bound sesquiterpene lactones, or any other possible type of sesquiterpene lactones. Accordingly, Appellants do not understand how any thermally extruded plant material of *Anantharaman* can have sesquiterpene lactones *included* therein when "[n]o sesquiterpene lactones [were] detected" at all. As such, Appellants submit that it is clear that *Anantharaman* fails to disclose or suggest a thermally extruded plant material that includes one or more phytochemical agents as required, in part, by the present claims.

Further, the Examiner asserts that "Appellants's instant specification also uses the same gelatinization process [as disclosed in *Anantharaman*] in making the claimed composition and

100% would be removed from the claimed invention as well.” See, Examiner’s Answer, page 8, lines 5-7. As support for this conclusion, the Examiner points to page 16 of the instant specification and column 4, lines 1-21 of *Anantharaman*. Appellant’s respectfully disagree and submit that simply because both processes are capable of using preconditioners and extruders, this does not mean that the manufacturing conditions are the “same” or “identical.”

For example, column 4 of *Anantharaman* states that the temperature of the preconditioner may be raised to a specific temperature, or a preconditioner may not be used at all. Further, *Anantharaman* also states that the extruder may be used at a temperature of 150 °C with a specific gauge pressure and possibly the introduction of water, steam or both. See, *Anantharaman*, column 4, lines 1-21. The skilled artisan would understand that using a preconditioner of a raised temperature and using no preconditioner at all would result in very different products. Additionally, the skilled artisan would also understand that materials need not be cooked at temperatures as high as 150 °C in order to gelatinize a starch. Accordingly, while some generic machinery may be used in both processes of the present disclosure and *Anantharaman*, the Examiner has not, and cannot, point to any disclosure in *Anantharaman* that indicates that the two processes are the “same” or “identical,” using exactly the same ingredients, combined in exactly the same way and manufactured exactly the same way with the same temperature, pressure, etc. Accordingly, the skilled artisan would immediately appreciate that changes in parameters such as moisture level, temperatures and pressures can dramatically change a resulting composition. The skilled artisan will also appreciate that changes in such parameters can easily affect the activity of a phytochemical agent such as, for example, sesquiterpene lactones.

Further, anticipation is a factual determination that “requires the presence in a single prior art disclosure of each and every element of a claimed invention.” *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. Because *Anantharaman* fails to disclose each and every element of the present claims, *Anantharaman* fails to anticipate the present claims.

For at least the reasons discussed above, *Anantharaman* fails to teach, suggest, or even disclose each and every element of Claims 1, 4, 6, 8 and 10 and thus, fails to anticipate the present claims. Accordingly, Appellants respectfully request that the rejections of Claims 1, 4, 6, 8 and 10 be reversed.

III. THE REJECTION OF CLAIMS 3, 11, 16 AND 63-64 UNDER 35 U.S.C. § 103(a) SHOULD BE REVERSED BECAUSE THE EXAMINER HAS NOT ESTABLISHED A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE CITED REFERENCES

Appellants respectfully request that the Board reverse the rejections of Claims 3, 11, 16 and 63-64 under 35 U.S.C. §103(a) because the Examiner has still failed to establish a *prima facie* case of obviousness with respect to the cited references. Appellants respectfully submit that the skilled artisan would have no reason to combine *Anantharaman* and *Hwang* to arrive at the present claims.

In the Examiner's Answer, the Examiner asserts that "[t]he examiner does not see evidence that it was the intent of *Anantharaman* to remove or destroy lactones" and submits that it was "the intent of *Anantharaman* to improve the palatability of food for dogs and cats through the process of gelatinization" and that *Anantharaman* only "surprisingly" found that gelatinization removed or destroyed lactones. See, Examiner's Answer, page 9, line 13-page 10, line 1. Appellants respectfully disagree and submit that the skilled artisan would not interpret *Anantharaman* as merely improving the palatability of a food for dogs and cats, but would appreciate the manner in which the palatability was improved (e.g., "remov[ing] or destr[y] the sesquiterpene compounds present in the inulin-containing plant material").

For example, in the Background section of *Anantharaman*, it is discussed in detail how the concentrations of sesquiterpene lactones in chicory or inulin taint products with bitter flavors that significantly reduce palatability of the product. Specifically, *Anantharaman* discloses the following:

[f]or the products which contain inulin, the inulin is usually purified from plants which contain higher concentrations of inulin; such as chicory, Jerusalem artichoke, leek and asparagus.

Otherwise, the plant material is treated in some form or another prior to use. A reason for the purification or treatment is that the plants themselves are reported to have bitter flavors which result in palatability problems; see for example U.S. Pat. No. 4,865,852. This is particularly the case with chicory where the bitter flavors are believed to be due to the concentrations of sesquiterpene lactones such as lactucin and lactucopicrin in chicory. Also, it is generally believed that more accurate control of the amounts added may be obtained with purified product. Various procedures for purifying the inulin or treating the plant material have been reported. Usually however they include the steps of chopping up the plant, extracting it, and hydrolyzing it with acids or enzymes. The hydrolysate is then collected and condensed to obtain the inulin.

See, *Anantharaman*, column 1, line 55-column 2, line 5. This disclosure explicitly discusses the need to remove the concentration of sesquiterpene lactones to increase palatability. Further, *Anantharaman* further states that it was found that adding “a natural plant material which is a source of inulin to the usual ingredients of gelatinized cereal products and then gelatinizing the ingredients does not adversely affect the palatability of the food to humans or pets.” *Anantharaman* specifically states, however, that the palatability was not affected because the “gelatinization of the ingredients of the cereal products surprisingly appear[ed] to remove or destroy the[] [sesquiterpene lactones].” See, *Anantharaman*, column 2, lines 26-35. *Anantharaman* went so far as to state that, regardless of the form of the cereal products, the matrix making up the cereal product “must be gelatinized in order to remove or destroy the sesquiterpene compounds present in the inulin-containing plant material.” See, *Anantharaman*, column 6, lines 29-33 (emphasis added). Accordingly, it is clear that the plant material of *Anantharaman* cannot include sesquiterpene lactones therein.

Further, testing using HPLC was done specifically to determine the content of free and bound sesquiterpene lactones in the final product of *Anantharaman*. As is clearly illustrated in at least Example 1 of *Anantharaman*, “[n]o sesquiterpene lactones [were] detected” in the final composition, whether free, bound or otherwise. See, *Anantharaman*, columns 6-7. Accordingly, Appellants do not understand how the Examiner asserts that *Anantharaman* is not directed to removal of sesquiterpene lactones but, rather, the increased palatability of foods for dogs and cats. Indeed, the skilled artisan would immediately appreciate that the removal of sesquiterpene lactones is exactly how *Anantharaman* increases said palatability.

As discussed in Appellant's Appeal Brief, in contrast to *Anantharaman*, *Hwang* is entirely directed toward the use sesquiterpene lactones obtained from plant material to suppress early proinflammatory cytokines and in ameliorating septic shock and other severe inflammatory disorders. See, *Hwang*, Abstract. Because *Anantharaman* includes processing steps designed specifically to remove or destroy sesquiterpene lactones such that no sesquiterpene lactones are present in the final composition, *Anantharaman*, therefore, specifically teaches away from the use of sesquiterpene lactones taught in *Hwang*.

Indeed, the Examiner assumes that it would have been within the ordinary skill of the artisan at the time the claimed invention was made to arrive at the presently claimed composition because the references relied upon allegedly teach that all aspects of the claimed invention were individually known in the art. However, this conclusory statement is not sufficient to establish a *prima facie* case of obviousness without some objective reason to utilize the teachings of the references to arrive at the invention. *Ex parte Levengood*, 28 USPQ 2d 1300 (Bd. Pat. App. & Inter. 1993). There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness by the Examiner. *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). This is definitely not the case wherein one reference is entirely directed to the removal or destruction of sesquiterpene lactones for purposes of palatability of a pet food, and the other is entirely directed to the use of sesquiterpene lactones to ameliorate septic shock and other severe inflammatory disorders in humans.

Further, references are not properly combinable or modifiable if their intended purpose is destroyed. For instance, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). This is exactly the case where *Anantharaman* is directed toward a matrix making up a cereal product that must be gelatinized in order to "remove or destroy the sesquiterpene compounds" present in the plant material (see, *Anantharaman*, col. 6, lines 30-34), and where *Hwang* is entirely directed toward using sesquiterpene lactones obtained from plant material (see, *Hwang*, Abstract).

Appellants respectfully submit that the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983);

In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). Further, one should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. (Fed. Cir. 1988).

IV. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the Final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the anticipation and obviousness rejections with respect to Claims 1, 3-4, 6, 8, 10-11, 16 and 63-64.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3714652-00365 on the account statement.

Respectfully submitted,

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